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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/641,378	08/13/2003	Binz DeWalch	D30473USC2 (PAT-DDD CIPA)	9613
7590 07/02/2007 DeWALCH TECHNOLOGIES, INC. 6850 WYNNWOOD LANE HOUSTON, TX 77008			EXAMINER KIM, SUN U	
			ART UNIT 1723	PAPER NUMBER
			MAIL DATE 07/02/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/641,378

Applicant(s)

DEWALCH, BINZ

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-97 is/are pending in the application.
- 4a) Of the above claim(s) 2-71 and 90-97 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 72-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 2-71 and 90-97 are withdrawn from further consideration pursuant to 37 CFR

1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/28/06.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Forsythe, Jr. et al (U.S. Patent No. 4,214,993). Forsythe, Jr. et al disclose a tube “32” having open and closed ends and a filtering means proximate the closed end of the tube “32”, i.e. “16” which includes filtering material (26) in a lower portion thereof “24” (see figure 1; col. 3, lines 6-40). Recitation of “for separating at least some nucleic acid from a fluid samples” is an intended use of a tube. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

4. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Shapiro (U.S. Patent No. 3,52,940). Shapiro discloses a tube “11” having open and closed ends and a filtering means “15” disposed adjacent a closed end thereof (see Figure 2; col. 2, lines 38-65). Recitation of “for separating at least some nucleic acid from a fluid samples” is an intended use of a tube. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to

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be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

5. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Card (U.S. Patent No. 4,643,981). Card discloses a tube “11” having a filtering means “15” disposed adjacent a closed end “12” thereof (see Figures 2, 5; col. 2, line 65 – col. 3, line 14). Recitation of “for separating at least some nucleic acid from a fluid samples” is an intended use of a tube. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

6. Claims 72-73, 81 and 87-89 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorn et al (U.S. Patent No. 3,875,012).

Regarding claims 72-73, Dorn et al disclose a tube comprising a hollow body (12) having a pierceable closed end (14) and a liquid filtering medium (42) i.e. retaining substance (see Figures 1, 4; col. 3, line 34 – col. 4, line 62). Recitation of “for processing substances and separating at least some nucleic acid from the substance” is an intended use of a vessel. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Regarding claim 81, Dorn et al teach a gel (see col. 4, lines 55-62).

Regarding claims 87-89, Dorn et al teach that a recess on the inside and in the center of the closed end of the tube which constitutes a groove (see Figure 1; col. 3, line 63 – col. 4, line 14).

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7. Claims 72-76, 83-84 and 87-89 are rejected under 35 U.S.C. 102(b) as being anticipated by Ayres et al (U.S. Patent No. 3,931,010).

Regarding claims 72-73, Ayres et al disclose a tube comprising a hollow body (12) having a pierceable closed end (16) and a filter i.e. retaining substance capable of filtering serum or plasma (Figure 1; col. 2, line 49 – col. 3, line 65). Recitation of “for processing substances and separating at least some nucleic acid from the substance” is an intended use of a vessel. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Regarding claims 74-76, Ayres et al teach waterproof filter paper, fibers and glass wool (col. 3, lines 57-63).

Regarding claims 83-84, Ayres et al teach that a gap interposed between the retaining substance (60) and the closed end of the tube (16) by a supporting means (32, 34) (Figure 2).

Regarding claims 87-89, Ayres et al teach that a recess on the inside and in the center of the closed end (16) of the tube (12) which constitutes a groove (Figure 1).

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 77 and 79-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayres et al as applied to claim 72 above and further in view of Kozak et al (U.S. Patent No. 5,460,974). Ayres et al teach a tube as described in above paragraph 10. Ayres et al teach the

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use of any suitable filter material chemically inert to blood and capable of filtering serum or plasma including fibrous or particulate material (col. 3, lines 57-63).

Claims 77 and 79-82 essentially differ from the tube of Ayres et al in reciting solid phase extraction media (claim 77), beads (claim 79), silica (claim 80), gel (claim 81) and surface coating (claim 82). Kozak et al teach various filter materials capable of separating plasma or serum from blood including silica gel, cellulosic beads (col. 15, line 59 – col. 16, line 53) and glass fiber matrix coated with agglutinin, coagulant or mixture thereof (col. 24, line 61 – col. 25, line 12). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute known filtering material as disclosed in Kozak et al for the filtering material of Ayres et al in the tube for separating serum or plasma from blood.

10. Claims 72-73, 75-77, 79, 81, 83-85 and 87-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forsythe, Jr. et al. in view of Finney et al (U.S. Patent No. 4,358,425).

Forsythe, Jr. et al disclose a centrifuge tube “32” having a closed end and a filtering material “26” i.e. a retaining substance in a filtering means “16” (Figures 1-2). Recitation of “for processing substances and separating at least some nucleic acid from the substance” is an intended use of a vessel. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim 72 essentially differs from the tube of Forsythe, Jr. et al in reciting a closed end being pierceable. Finney et al teach a centrifuge tube with a pierceable bottom (Figure 1; col. 2, lines 16-42). It would have been obvious to a person of ordinary skill in the art at the time the

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invention was made to modify the tube of Forsythe, Jr. et al to incorporate a pierceable bottom at the closed end of the tube to extract desired constituents from the tube as suggested by Finney et al (col. 2, lines 37-43).

Regarding claim 73, Forsythe, Jr. et al teach a filter "26" (Fig. 1; col. 4, lines 46-50).

Regarding claims 75-77, 79 and 81, Forsythe, Jr. et al teach polyester fiber, glass beads, ion exchange resins and agarose gel beads (col. 4, lines 10-54).

Regarding claims 83-85, Forsythe, Jr. et al teach that the filtering material "26" is spaced above the closed end of the tube "32" by linear projections "29" disposed radially from the center of the closed end of the tube "32" (Figure 2; col. 4, lines 1-9).

Regarding claims 87-88, Forsythe, Jr. et al teach that the closed end includes a recess generally in the center thereof (col. 3, lines 64-68).

11. Claims 72-74, 76, 78 and 83-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro in view of Finney et al. Shapiro discloses a tube "11" having a closed end and a retaining substance (Figure 1). Recitation of "for processing substances and separating at least some nucleic acid from the substance" is an intended use of a vessel. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim 72 essentially differs from the tube of Shapiro in reciting a closed end being pierceable. Finney et al teach a centrifuge tube with a pierceable bottom (Figure 1; col. 2, lines 16-42). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the tube of Shapiro to incorporate a pierceable bottom at the

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closed end of the tube to extract desired constituents from the tube as suggested by Finney et al (col. 2, lines 37-43).

Regarding claim 73, Shapiro teaches a filter "15" (Fig. 1).

Regarding claims 74, 76 and 78, Shapiro teaches glass filter paper cup "41" (Fig. 4; col. 3, lines 50-67).

Regarding claims 83-84, Shapiro teaches that the filtering material "15" is supported above the closed end of the tube "11" by shoulder "31" (Figure 2; col. 3, lines 68-75).

12. Claims 72-73, 83-84 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savas et al (U.S. Patent No. 4,800,020) in view of Finney et al. Savas et al disclose a tube "C" having a closed end and retaining substance "64" (Figure 5). Recitation of "for processing substances and separating at least some nucleic acid from the substance" is an intended use of a vessel. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim 72 essentially differs from the tube of Savas et al in reciting a closed end being pierceable. Finney et al teach a centrifuge tube with a pierceable bottom (Figure 1; col. 2, lines 16-42). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the tube of Savas et al to incorporate a pierceable bottom at the closed end of the tube to extract desired constituents from the tube as suggested by Finney et al (col. 2, lines 37-43).

Regarding claim 73, Savas et al teach a filter "64" (Fig. 5; col. 4, lines 42-50).

Regarding claims 83-84 and 86, Savas et al teach that the filtering material "64" is spaced above the closed end of the tube "C" by linear projections "29" disposed radially from the center of the closed end of the tube "32" by accurate circular projection "24" to provide gap between the filter "64" and the closed end of the tube "C" (col. 3, lines 64-66 and col. 4, lines 65-67).

13. Applicant's arguments filed 5/14/07 have been fully considered but they are not persuasive. In response to applicant's argument that Shapiro, Card and Forsythe references does not disclose separating at least some nucleic acid, a recitation of the intended use of the claimed invention (e.g. for separating at least some nucleic acid from the substance) must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Presently, claims do not claim any filter means or a retaining substance for selectively retaining nucleic acid but only claims retaining a desired substance. Shapiro, Card or Forsythe has filtering material that selectively retains a desired substance.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. This application contains claims 2-71 and 90-97 drawn to an invention nonelected with traverse in the reply filed on 8/28/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is 571-272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read "John Kim".

John Kim

Primary Examiner

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JK

November 8, 2006